

PSJ3

Exhibit 406



**U.S. Department of Justice
Drug Enforcement Administration**

Office of the Administrator

Springfield, Va 22152

FEB 02 2012

IN THE MATTER OF

Cardinal Health
2045 Interstate Drive
Lakeland, Florida 33805

**ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION**

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Cardinal") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration RC0182080, pursuant to 21 U.S.C. § 824(d), because such registration constitutes an imminent danger to the public health and safety. Notice is also given to afford Cardinal an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, or a location designated by the Administrative Law Judge, on April 3, 2012 (if Cardinal requests such a hearing), as to why DEA should not revoke Cardinal's DEA Certificate of Registration RC0182080, pursuant to 21 U.S.C. § 824(a)(4), deny any pending applications for renewal or modification of such registration, and deny any applications for additional registration, pursuant to 21 U.S.C. § 823(f), because Cardinal's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. Cardinal is registered with DEA as a distributor in Schedules II-V pursuant to DEA Certificate of Registration RC0182080 at 2045 Interstate Drive, Lakeland, Florida 33805. DEA Certificate of Registration RC0182080 expires by its terms on August 31, 2012.
2. On September 30, 2008, Cardinal entered into an Administrative Memorandum of Agreement (MOA) with DEA agreeing to "maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations." Furthermore, Cardinal "acknowledg[ed] and agree[d] that the obligations undertaken ... do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for

controlled substances.” MOA, at 3.

3. Despite the MOA, the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1).

4. Since at least 2009, Cardinal’s largest purchasers of oxycodone products have been retail pharmacies in the State of Florida engaged in a scheme to distribute controlled substances based on purported prescriptions that were issued for other than a legitimate medical purpose and outside the usual course of professional practice.

- a. From January 1, 2008 through December 31, 2011, Automation of Reports and Consolidated Orders System (“ARCOS”) data shows that Cardinal’s sales of oxycodone products to its top four retail pharmacy customers exceeded 12.9 million dosage units. In 2010 and 2011 alone, Cardinal sold 10.9 million dosage units of oxycodone to its top four customers. From 2008 to 2009, Cardinal’s sales to its top four retail pharmacy customers increased approximately 803%. From 2009 to 2010, Cardinal’s sales to its top four retail pharmacy customers increased approximately 162%.

The egregious quantities of oxycodone distributed by Cardinal to its top four retail pharmacy customers well exceeded the amount of oxycodone distributed to Cardinal’s Florida retail pharmacies, which received, on average, approximately 5,347 dosage units of oxycodone per month.

- b. From January 1, 2008 through December 31, 2011, Cardinal sold over 5 million dosage units of oxycodone to its top customer, Holiday CVS, L.L.C., d/b/a CVS/Pharmacy # 00219 (“CVS 219”) (DEA Certificate of Registration BC5289055). On average, Cardinal sold CVS 219 approximately 137,994 dosage units of oxycodone per month during the same time period.
- c. From January 1, 2008 through September 30, 2011, Cardinal sold approximately 3.4 million dosage units of oxycodone to Gulf Coast Pharmacy (former DEA Certificate of Registration BG8830223). On average, Cardinal sold Gulf Coast Pharmacy approximately 96,664 dosage units of oxycodone per month during the same time period.
- d. From January 1, 2008 through December 31, 2011, Cardinal sold approximately 2.2 million dosage units of oxycodone to Holiday CVS, L.L.C., d/b/a CVS/Pharmacy #05195 (“CVS 5195”) (DEA Certificate of Registration BC6988298). On average, Cardinal sold CVS 5195 approximately 58,223 dosage units of oxycodone per month during the same time period.

- e. From January 1, 2008 through September 30, 2011, Cardinal sold approximately 2.1 million dosage units of oxycodone to Caremed Health Corporation, d/b/a Brooks Pharmacy ("Brooks Pharmacy") (former DEA Certificate of Registration BC7126457). On average, Cardinal sold Brooks Pharmacy approximately 59,264 dosage units of oxycodone per month during the same time period.
5. Notwithstanding the large quantities of controlled substances ordered by Cardinal's top retail pharmacy customers, Cardinal failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels, including Cardinal's failure to conduct due diligence of its retail pharmacy chain customers. Furthermore, Cardinal failed to detect and report suspicious orders of oxycodone products by its pharmacy customers, as required by 21 C.F.R. §1301.74(b). In addition, Cardinal's conduct described herein violated the provisions of the Administrative Memorandum of Agreement.

6. In addition to the legal authorities cited above, the following Final Order provides a summary of the legal basis for this action: *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), it is my preliminary finding that Cardinal's continued registration is inconsistent with the public interest. Under the facts and circumstances described herein, it is my conclusion that Cardinal's continued registration while these proceedings are pending constitutes an imminent danger to the public health and safety. See 21 U.S.C. § 824(d). Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RC0182080 is hereby suspended, effective immediately. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Cardinal possesses pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession Cardinal's DEA Certificate of Registration RC0182080 and any unused order forms.

THE following procedures are available to you in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Cardinal may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. See 21 C.F.R. § 1301.43(a). If Cardinal fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Cardinal may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. See 21 C.F.R. § 1301.43(c).

3. Should Cardinal decline to file a request for a hearing or, should Cardinal request a hearing and then fail to appear at the designated hearing, Cardinal shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing, and I may enter my final order in this matter without a hearing based upon the evidence presented to me. See 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. See 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrisette Drive, Springfield, VA 22152.



Michele M. Leonhart
Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Dedra S. Curteman, Counsel for the Government
Carrie A. Bland, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

**DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrissette Drive
Springfield, Virginia 22152**

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]**
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]**
- (C) [State briefly the position of the person with regard to the particular objections or issues.]**
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]**

Respectfully yours,

[Signature of registrant, applicant or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.